510(k) Summary

JAN 25 2010

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Date Prepared:	June 3, 2009
Device Trade Name:	AnyPlus Spinal Fixation System
Common Name	Spinal interlaminal fixation orthosis Spinal intervertebral body fixation orthosis Pedicle Screw spinal system
Classification Name, Number & Product Code:	Class II: appliance, fixation, spinal interlaminal, 888.3050, KWP Class II: appliance, fixation, spinal intervertebral body, 888.3060, KWQ Class II/Class III: orthosis, spondyloisthesis spinal fixation, 888.3070, MNH, MNI, NKB
Predicate Devices:	GSS Pedicle Screw System (K053573), Synthes Pangea System (K052123) INCOMPASS SPINAL FIXATION SYSTEM (K021564)
Device Description and Statement of Intended Use	Device Description: The AnyPlus Spinal Fixation System consists of various hooks, screws, rods and connectors and is intended to create a rigid spinal construct. A table of components can be found in Section 11. The AnyPlus Spinal Fixation System includes components from GSS Pedicle Screw System previously cleared in K053573. These components will keep their original cleared trade name. A table of components can be found in Section 11 identified as GSS Pedicle Screw System 510(k): K053573. The components are manufactured from Ti6Al4V ELI according to ISO 5832-3 and ASTM F-136. The screws are available from 4.0 to 10.5mm diameters with lengths ranging from 20 to 100mm (Length does not include the screw head). Specialized instruments are available for the application and removal of the Anypluss Spinal Fixation System. A table of components can be

found in Section 11.

Intended Use: *AnyPlus Spinal Fixation System* are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion

Summary of Technological Characteristics

AnyPlus Spinal Fixation System is made of devices for fixation of the non cervical spine. They include smooth rods, plates, screws, hooks, nut screws, transverse links. The components are manufactured from Ti6Al4V ELI according to ISO 5832-3 and ASTM F-136. The screws are available from 4.0 to 10.5mm diameters with lengths ranging from 20 to 100mm (Length does not include the screw head).

Conclusion

The information discussed above demonstrates that AnyPlus Spinal Fixation System, as effective, and performs as well as or better than the predicate devices.

Declarations

This summary includes only information that is also covered in the body of the 510(k).
This summary does not contain any puffery or unsubstantiated labeling claims.

Summary of Technical Characteristics

Feature	AnyPlus Spinal Fixation System	GSS Pedicle Screw System	Synthes Pangea System	INCOMPASS SPINAL FIXATION SYSTEM
510(k) Number	K091717	K053573	K052123	K021564
Manufacturer	GS MEDICAL CO., LTD.	GS MEDICAL CO., LTD.	SYNTHES (USA)	SPINAL CONCEPTS, INC
Classification # & Product Code	888.3050, 888.3060, 888.3070 KWP, KWQ, MNH, MNI	888.3070 MNH, MNI	888.3050 888.3070 KWP, KWQ, MNH, MNI, NKB	888.3060 KWP, KWQ, MNH, MNI
Intended Use	*AnyPlus Spinal Fixation System* are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system	The GSS Pedicle Screw System is a pedicle screw system indicated for the treatment of severe Spondylisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous	The Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea™), Click'X® Monoaxial, Dual-Opening and the Small Stature USS (which	When intended for pedicle screw fixation from T1-S1, the InCompass Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature

	(T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.	bon graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the GSS Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative Spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis).	includes small stature and pediatric patients) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion. When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle	patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, and failed previous fusion. As a pedicle screw system placed between L3 and S1, the indications include Grade 3 and 4 spondylolisthesis, when utilizing autologous bone graft, when affixed to the posterior lumbosacral spine, and intended to be removed after solid fusion is established. When intended for non-pedicle, posterior screw fixation of the non-cervical spine (T1-S1), the indications are idiopathic scoliosis, neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity, scoliosis with deficient posterior elements

			screw construct. When used with the 3.5/6.0 mm parallel connectors, the Synthes USS (including the Click'X® and, USS VAS variable axis components, and Pangea™), Click'X® Monoaxial and Dual-Opening USS can be linked to the CerviFix® System. In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea™), the Click'X® Monoaxial and Dual-Opening USS Systems. In addition, Synthes USS (including the Click'X®, and USS VAS variable axis components, and Pangea), Click'X® Monoaxiala and the Dual-Opening USS can be interchanged with all USS 6.0 mm rods and transconnectors.	such as that resulting from laminectomy or myelomeningocele, spinal fractures (acute reduction or late deformity), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), tumor, spondylolisthesis, spinal stenosis and failed previous fusion. When intended for anterioateral screw, rod and or cable fixation of the T6-L5 spine the indications are degenerative disc disease disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor and failed previous fusion. The use of posterior spinal instrumentation in children has been reported in the literature. The InCompass Spinal Fixation System may be used for non-pedicle posterior use in this patient group. After solid fusion occurs, these devices serve no functional purpose

				and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and patient, taking into consideration the patient's general medical condition and the potential risk to the patient for a second surgical procedure.
Material	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy (Ti-6Al-4V ELI)	Titanium Alloy	Titanium Alloy (Ti-6Al-4V ELI)
Standard of Conformity	ASTM F1717-04, ASTM F1798-97, ASTM F136-98, ISO 5832-3:1996, ANSI/AAMI/ISO 17665-1			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

GS Medical Co., Ltd.
% Qserve America, Inc.
Mr. William F. Greenrose
President
220 River Road
Claremont, New Hampshire 03743

JAN 25 2010

Re: K091717
Trade/Device Name: AnyPlus Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWP, KWQ, MNH, MNI
Dated: January 10, 2010
Received: January 12, 2010

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091717

Device Name: AnyPlus Spinal Fixation System

Indications For Use:

AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2), a posterior hook fixation system (T1-L5), or as a anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091717